27 October 2022

Botanix Quarterly Activity Report and 4C Quarterly Cash Flow Report

Key highlights

- **Submission of New Drug Application (NDA) for FDA approval for Sofpironium Bromide successfully completed**
- **Successful A$7.5m placement to institutions and sophisticated investors, including directors of the Board**
- **Positive data announced for BTX 1702 rosacea Phase 1b/2 randomised, double blinded, vehicle-controlled clinical study**
- **$10.1 million cash at end of quarter**

Philadelphia PA and Phoenix AZ, 27 October 2022: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to release its Quarterly Activity Report and Appendix 4C Quarterly Cash report for the period ended 30 September 2022.

The Company has strengthened its position as a leading clinical dermatology company with the announcement on 26 September 2022 of the submission of a New Drug Application (NDA) for our lead product, Sofpironium Bromide, to the U.S. Food and Drug Administration (FDA) for approval. This submission was supported by a successful A$7.5 million placement to institutional and sophisticated investors at the end of August 2022, with A$0.5 million of the placement made to Board directors, which issue is planned to be approved at the Company's upcoming Annual General Meeting. Finally, subsequent to the quarter end, the Company also announced positive data from its BTX 1702 rosacea Phase 1b/2 clinical study, which demonstrated clinically meaningful results for the active arms versus vehicle (placebo) and good tolerability and safety.

All of these recent achievements represent important milestones for Botanix and assist in helping to transition the Company towards a commercial stage dermatology company.

Sofpironium Bromide NDA Submission

Sofpironium Bromide is a new chemical entity developed to be a best-in-class, once daily, topically administered therapy for the treatment of primary axillary hyperhidrosis. Sofpironium Bromide blocks sweating, by binding to the receptor and thereby blocking the sweat signal, with recent Phase 3 studies demonstrating that approximately 85% of patients using Sofpironium Bromide experienced a clinically meaningful improvement in their condition over the course of the studies. Based on these studies, the Company believes that Sofpironium Bromide has the potential to be the best-in-class treatment for axillary hyperhidrosis.

On 26 September 2022, Botanix announced that the NDA was submitted to the FDA for approval of Sofpironium Bromide. Sofpironium Bromide is an exciting opportunity, with more than 15 million

patients that suffer from hyperhidrosis in the US alone.[1] Existing therapies are not ideal, either because of the lack of efficacy, unfavourable side effect profile, risk of drug exposure to the skin, or pain from invasive procedures or surgery.

Botanix expects the FDA to adopt the usual 12 month review period, and is undertaking a number of activities to support FDA review and related inspections, as well as accelerate its plans for commercial launch of the product following FDA approval.

Sofpironium Bromide has already been licensed to Botanix's partner, Kaken Pharmaceuticals in Japan, who have already secured approval of Sofpironium Bromide 5% for the treatment of primary axillary hyperhidrosis from the Japanese equivalent of the FDA, the Pharmaceuticals and Medical Devices Agency ("PMDA").

Clinical Studies and Drug Development

BTX 1702: Papulopustular Rosacea

Subsequent to quarter end, Botanix announced positive data from its BTX 1702 papulopustular rosacea Phase 1b/2 clinical study, which showed statistical significance in the FDA designated endpoint of reduction in inflammatory lesions and also approached statistical relevance for the investigator's global assessment "IGA for papules and pustules" (grade of 0 or 1 at day 57, p=0.059 and 2 grade improvement from baseline, p=0.059).

The randomised, double blind, vehicle-controlled study was designed to investigate the safety and tolerability of BTX 1702 in adults over an 8-week treatment period, with two different concentrations of BTX 1702. The Study enrolled 133 patients, aged 18 to 65 years old with moderate to severe papulopustular rosacea, in 16 dermatology clinical sites across Australia and New Zealand. Patients were randomised into 3 separate treatment groups consisting of BTX 1702 10% gel (n=45), BTX 1702 20% gel (n = 45) and vehicle gel (control n= 43) – all applied twice daily.

All arms (vehicle gel, 10% and 20% BTX 1702 gel) were safe and well tolerated with no serious adverse events observed during the study. From an efficacy perspective, both doses of BTX 1702 showed clinically positive results, with the 10% showing greater results, being statistically significant compared to vehicle, for reductions in inflammatory lesion counts and improvement in investigator's global assessment (IGA) endpoints.

Available data from competitive products that have published efficacy outcomes after 8 weeks of treatment, suggests that 10% BTX 1702 is comparable in lesion reduction and IGA improvement at the same point in time, with a possible improvement in safety and tolerability.[2] Separately, the reduction in redness, as measured by the CEA outcome compares very favourably with products designed to reduce redness.[3]

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[1] Reports and Data, Hyperhidrosis Treatment Market by Treatment Type, By Disease Type, By End User, By Regional Outlook and Segment Forecasts 2022

[2] See Prescribing information for https://www.galderma.com/us/sites/default/files/2019-01/Soolantra_Cream_PI.pdf and https://www.galderma.com/us/sites/default/files/2022-03/Epsolay_PI.pdf as an example

[3] See Prescribing Information for https://www.rhofade.com/_assets/pdf/Rhofade-PI_201-11-13.pdf as an example

The market for treatments for rosacea (including papulopustular) is expected to reach US$2.6 billion by 2025 and is growing at a CAGR of 6.8%.[4] Rosacea affects more than 430 million people worldwide and the global incidence among adults is estimated at 5.5% with the majority of patients consisting of women over the age of 35 years.[5] There are currently more than 16 million Americans affected by the illness with approximately 5 million medical treatment prescriptions in the US alone each year.[6]

There is currently a need for new rosacea treatments and BTX 1702 has the potential combine reduction in inflammatory lesions, antimicrobial effects and general improvement in skin condition in a single product.

Botanix will review the full data set for the Study once the final clinical study report is completed and the Company has had the opportunity to engage with the FDA on the development program.

BTX 1204A: Canine atopic dermatitis

Subsequent to quarter end, Botanix also confirmed that the BTX 1204A canine atopic dermatitis pilot study has completed. Based on an initial analysis, the Company may not be able to gain significant efficacy data from the study as a substantial number of dogs enrolled did not meet the specific inclusion criteria. Both endpoints, safety and tolerability, for the BTX 1204A study were positive with no serious adverse events observed. Therefore, Botanix will continue to review the clinical data collected and if any additional insights are possible to be gained from this pilot study.

The success of the BTX 1702 study significantly adds to the Botanix pipeline of dermatology products and with the recent submission of Sofpironium Bromide for FDA approval, helping to accelerate Botanix's transition to a revenue generating dermatology company.

Corporate

In early September 2022, Botanix announced it received firm commitments from new and existing institutional and sophisticated investors for the placement of 113,636,364 fully paid ordinary shares at A$0.066 per New Share to raise up to $7.5m in gross proceeds in an oversubscribed placement.

All directors committed to participate in the Placement, for a total of $0.5 million of Ordinary Shares as part of the Placement, which is subject to shareholder approval at the Company's upcoming Annual General Meeting. Directors are not being issued New Options as part of their participation in the Placement.

The proceeds from the Placement will be used to progress Botanix's lead development program, Sofpironium Bromide gel (15%), including costs associated with filing for FDA approval, preparing for commercial launch in the United States, enhancing quality and manufacturing capabilities, as well as general working capital purposes.

[4] Grand View research January 2019
[5] Gether L, et al. Br J Dermatol. 2018;179:282-289;
[6] National Rosacea Society. www.rosacea.org; and Symphony Health Solutions, PHAST

Financial Overview

During the quarter, Botanix had net cash outflows from operating activities of A$5.4m, with $1.5m expended on activities associated with accelerating the filing for FDA approval of Sofpironium Bromide, as well as A$3.3m invested in R&D activities for the balance of the Company's dermatology assets. At the end of the quarter the Company had a cash balance of $10.1m. Subsequent to quarter end the Company received its R&D refund of $3.7 million part of which was used to repay the $1.85m drawdown facility provided by Radium Capital against the expected refund.

Payments to related parties as detailed in Section 6.1 of the Appendix 4C relate to salaries, fees and superannuation (or equivalent) entitlements paid pursuant to agreements with Directors or associates.

Release authorised by the Board

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is committed to the development of novel treatments for a range of common skin diseases. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide, for the treatment of primary axillary hyperhidrosis, filed for FDA approval in Q3 CY2022 with approval expected in Q3 2023. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea (successful Phase 1b/2 study in 4Q 2022), dermatitis and acne respectively. Botanix is also developing a topical antimicrobial product for the eradication of bacteria on the skin surface, initially in patients who are undergoing hemodialysis.

Botanix leverages its proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which is utilised in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. To learn more please visit: http://www.botanixpharma.com/

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Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Botanix Pharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
70 009 109 755	September 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	278	278
1.2	Payments for		
	(a) research and development (inc allocated staff costs)	(3,319)	(3,319)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) other staff costs	(400)	(400)
	(f) administration and corporate costs	(472)	(472)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	5
1.5	Interest and other costs of finance paid	(7)	(7)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (Sofpironium Bromide FDA filing and associated costs including allocated staff costs)	(1,492)	(1,492)
1.9	**Net cash from / (used in) operating activities**	(5,407)	(5,407)

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (Acquisition of Sofpironium Bromide assets)	(183)	(183)
2.6	**Net cash from / (used in) investing activities**	**(183)**	**(183)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,000	7,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(420)	(420)
3.5	Proceeds from borrowings	1,850	1,850
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payment for right-of-use asset)	(44)	(44)
3.10	**Net cash from / (used in) financing activities**	**8,386**	**8,386**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,286	7,286
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,407)	(5,407)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(183)	(183)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	8,386	8,386
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	**Cash and cash equivalents at end of period**	**10,081**	**10,081**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	10,081	10,081
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**10,081**	**10,081**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	389
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end[(1)] $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	1,850[(1)]	1,850
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**1,850**	**1,850**

7.5	**Unused financing facilities available at quarter end**	-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

[(1)]Botanix set up a loan facility in July 2022 for $1,850,000 with Radium Capital secured against its R&D Tax Incentive claim with an interest rate of 15% per annum.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(5,407)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,081
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,081
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.86

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: With the conclusion of the BTX1702 study and the completion of the filing of the FDA approval for Sofpironium Bromide, it is expected the related operating expenses will reduce.

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The Company notes the receipt of its Research and Development incentive refund post quarter end (see announcement 26/10/2022). In addition, the Company is currently undertaking a capital raising (see announcement 27/10/2022).

8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?
Answer: Yes see above.	

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 27 October 2022

Authorised by: Simon Robertson
Company Secretary
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.